Informed Consent and Consent Forms for Research Participants

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Informed consent is a communication process by which researchers reach agreement with people about whether they wish to participate in research. Confusing informed consent with a signed consent form may violate the ethical intent of informed consent, which is to communicate clearly and respectfully, to foster trust, comprehension, and good decision making, and to ensure that participation is voluntary.

Consent forms are often written in “legalese” and are long, complex, and often inappropriate to the culture or language of the potential subject, insulting, and virtually impossible for most people to comprehend. They convey to some the impression that signing such a formal-looking document commits them to participation. Among subjects who willingly sign documents, most sign the consent form without reading it.

How has this come to pass? Early concern with ethics of human research was about biomedical research and focused on the necessity of obtaining informed consent. Over the decades, the elements of informed consent have grown in number, as has the idea that informed consent is a form that is to be signed by the subject. According to the Federal Regulation of Human Research 46.117(a):

Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form.

However, many researchers and the Institutional Review Boards that govern their research fail to recognize that 46.117(c) provides for a waiver of signed consent forms:

> *(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:*
> *(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern, or*
> *(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.*

The reason for obtaining a signed consent form has always been much more to protect the researcher and the institution than to serve the interests of the research subject. In case the subject claims later that consent was inadequate or omitted, the researcher can counter by showing the form. Recently, the Office of Human Research Protection has imposed highly publicized and costly sanctions against a few research institutions. Understandably, IRBs and research administrators consider it in their self-interest to make highly conservative decisions. Since IRBs must take steps to justify waiving documentation of

informed consent by deeming the research to be minimal risk, many consider it safer not to do so, fearing that such an action might leave them open to questions by the OHRP. Thus, the reason for obtaining a signed consent form is typically to protect the institution, not the subject. Researchers, science, institutions, subjects, and IRBs would all be better off if they made intelligent interpretations of the requirements of the Common Rule.

The Social and Behavioral Sciences Working Group has made various recommendations based on the Common Rule, designed to guide social and behavioral researchers and IRBs out of such conundrums. The authors, both members of the Working Group, developed recommendations concerning informed consent, some of which are summarized here:

1. Informed consent should take the form of an open, easily understood communication process. Typically, this means a friendly verbal exchange between researcher and subject, with a written summary of the information for the subject to keep, as appropriate. (The copy for the subject to keep would be inappropriate if the written record of the subject's participation could be damaging to the subject, as when the research is about domestic violence, or illegal behavior). Both the verbal and written discussion should be brief, and simply phrased at such a level that all of the subjects can understand it.

2. Subjects must receive enough easily understood, accurate information to judge whether the risk or inconvenience involved is at a level they can accept. The responsibility rests with the investigator to describe any risks accurately and understandably. There are many kinds of minor or everyday risks or inconveniences that most persons would gladly undertake if it were their choice to do so, but which they would not wish to have imposed upon them unilaterally. However, some may make a rational decision that the experience would be too stressful, risky, or unpleasant for some idiosyncratic reason that applies to them and not to other subjects.

3. Especially when the research procedure is long and complex, the researcher must make it quite clear that the subject is free to ask questions at any time. Informed consent, as a conversation (not a form), needs to be available throughout the research, as subjects do not necessarily develop questions or concerns about their participation until they are well into the research experience. For example, a discussion of confidentiality may not capture subjects' attention or comprehension until they are asked some quite personal questions in the ensuing research experience.

4. When subjects can readily refuse to participate by hanging up the phone or tossing out a mailed survey, the informed consent can be extremely brief (a sentence or two). Courtesy and professionalism require that the identity of the researcher and research institution be mentioned, along with the nature and purpose of the research. However, if there are no risks, benefits, or confidentiality issues involved, these topics and the right to refuse to participate need not be mentioned, as such details would be gratuitous and might decrease participation by implying greater risk that actually exists. If the researcher has any connection with the institution at which the subjects receive health care or other essential services, it is necessary to mention the right of the research subject to refuse or withdraw without prejudice. Such rights may be honored implicitly by making it clear that you are asking their permission to involve them as research subjects.

5. Verbal informed consent need not be detailed and written consent is not appropriate when the research

is not concerned with sensitive personal information and when subjects are peers or superiors of the researcher.

6. The cultural norms and life-styles of subjects should be considered when deciding how to approach informed consent. For example, research on homeless injection drug users should probably be preceded by a several week-long process of “hanging out” and talking with them. The resulting informal communication will raise issues they wish to discuss with the researcher. The conditions under which the research is conducted can then be negotiated orally between the researcher and the community members, as appropriate. Written documents and signed forms would expose subjects to risk of arrest and serve no redeeming purpose.

7. A wide range of media are appropriate for administering informed consent. Video tapes, brochures, group discussions, web sites, community newsletters, and the “grape vine” can be more appropriate ways of communicating with potential subjects than the potentially confusing formal consent forms that often are used.

8. When written or signed consent places subjects at risk, it must be waived. There are times when the written record is the only evidence that the subject has participated in a study in which there is acknowledgement or appearance of situations that would place the subject at risk.

9. When it is important to have some record of the informed consent but when written or signed consent would place the subject at risk or be difficult for the subject to read, one useful procedure is to have a trusted colleague witness the verbal consent.

10. Community consultation, or meeting with community leaders of the potential subjects, is a useful way to plan research that is likely to raise sensitive questions among those to be studied and members of their community. This is not a substitute for individual informed consent, but often clears the way for potential subjects to be ready to decide whether to participate.

11. In certain circumstances, persons are not in a position to decide whether to consent until immediately after their participation, e.g., in brief sidewalk interviews, which persons are likely to welcome.

12. Some research cannot validly be conducted if all details are disclosed at the outset. The alternatives to outright deception of subjects are to a) obtain permission to provide only a description of what the subject will experience, with an agreement that the full details of the study will be disclosed afterward; b) obtain permission to engage in concealment or deception with the understanding that pilot research has shown that peers of the subject do not find such concealment or deception objectionable and that a full explanation will follow their participation, c) explain that the subject might be enrolled in one of several possible conditions and to gain permission to disclose in which of these the subject was actually enrolled after his or her participation is completed.

Author’s Note: The Social and Behavioral Sciences Working Group (formerly a part of the National Human Research Protections Advisory Council but now an independent body) chaired by Felice Levine helped to develop these ideas.

Reference

Melton, G., Levine, R. J., Koocher, G., Rosethal, R., & Thompson, W. (1988). Community Consultation in Socially Sensitive Research: Lessons from Clinical Trials on Treatments for AIDS. *American Psychologist*, 43, 573-581.